VA Department of Veterans Affairs	VA RESEARCH CONSENT FORM Version A

Subject Name: _____ Date: _____

Title of Study: Telemedicine Intervention to Improve Depression Care in Rural CBOCs

Principal Investigator: Dinesh Mittal, M.D. VAMC:
Co-Principal Investigator: Rafael Torres, M.D.

INTRODUCTION

You are being asked to participate in a research study to learn more about people with depression and how the care they receive at the VA Community Based Outpatient Clinics (CBOCs) affects symptoms of depression. You will be given a copy of this consent form at your regular primary care clinic appointment.

PURPOSE OF STUDY

The purpose of this research is to study how we can use telemedicine to improve treatment for people with depression who live a long distance from a VA medical center. By telemedicine, we mean using a telephone, interactive video (a video camera connected to a TV) and computerized medical records to improve your access to care. You were selected as a possible participant in this study because you currently have an appointment at the CBOC and you have symptoms of depression. Approximately 590 primary care patients who are feeling depressed will be enrolled in the study from Arkansas, Louisiana, Mississippi and Texas.

The study will compare the quality of depression treatment in VA Community Based Outpatient Clinics (CBOCs) including Mountain Home AR, El Dorado AR, Hot Springs AR, Monroe LA, Longview TX, Hattiesburg MS and Meridian MS. Half of the CBOCs were randomly assigned (like the toss of a coin) to receive extra telemedicine-based treatments including: patients participating in the study will receive educational materials about depression, and occasional telephone calls from a nurse (and perhaps a clinical pharmacist) who will ask questions about depression symptoms, discuss the effects of any antidepressant medications that might have been prescribed, and make treatment recommendations to the study participant's regular primary care doctor. The purpose of this study is to determine whether these extra efforts improve depression symptoms.

SUBJECT'S IDENTIFICATION (I.D. plate of give name- last, first, middle)

G.V. (Sonny) Montgomery VAMC
Institutional Review Board
FULL BOARD APPROVAL
Date Approved: 2-5-04
Expiration Date: 2-5-05
IRB Initials JGW

VA FORM

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PROCEDURES

If you agree to be a part of this study, the following will happen to you.

1. You will be asked to complete three research interviews over the phone. Your first research interview will consist of a one-hour interview to determine your overall health status and the severity of your depression. Follow-up one-hour phone interviews will take place 6 and 12 months later. You will be compensated for your time.

2. The research team will review your medical records to see what services and treatments you are receiving currently and what other treatments you may receive over the next year.

3. You will be called by a nurse or clinical pharmacist every two weeks after the first research interview until symptoms of depression have been gone for 6 months. In these shorter interviews, you will also be asked about depression symptoms and depression treatment. During these shorter interviews, the nurse will give you information about depression and you can ask questions. The information about your depression from the shorter interviews will be passed on to your regular primary care doctor along with recommended medications. Information and recommendations will be communicated to your doctor using the Computerized Patient Record System (CPRS) which is the VA's main way of storing and communicating clinical information.

4. Your regular primary care doctor may recommend a referral for a face-to-face appointment to see a psychiatrist at the VA Medical Center or recommend an interactive video consult with a psychiatrist. You may choose either of the two options or neither option. If you choose the interactive video consult, you will go to the CBOC and talk to a psychiatrist who is at the nearest VA Medical Center using a video camera connected to a TV. The psychiatrist may then make treatment recommendations to your primary care doctor.

5. The study will continue for up to one year. During this study, you and your regular primary care doctor will be in charge of your treatment. The research team will only make treatment recommendations, not final treatment decisions or changes. Your doctor is under no obligation to follow the treatment recommendations. You and your regular primary care doctor will make final treatment decisions. At any time, you can choose not to be treated or choose some other type of treatment like counseling. At any time, you or your primary care doctor can make an appointment for you to be seen at the Mental Health Clinic at the VA Medical Center.

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BENEFITS

If you agree to take part in this study, there may or may not be a direct medical benefit to you. We hope the information learned from this study will benefit other patients with depression in the future.

RISKS

Your participation in the protocol involves the following risks:

1) inconvenience of time and emotional upset
2) loss of privacy

VOLUNTARY PARTICIPATION

Participation in research is entirely voluntary. You may refuse to participate or withdraw at any time without jeopardy to the medical care you will receive at this institution or loss of benefits to which you are entitled. Signing this form does not mean that you lose any legal rights to which you are entitled. Although it is not likely, Dr. Mittal or Dr. Torres may end the study or your participation in the study at any time.

COSTS

You will not incur any expenses related to participating in this study. If you normally have to pay copayments when you receive care at the VA, you may be asked to make a copayment at your visits including visits for interactive video consults.

QUESTIONS, CONCERNS OR ADVERSE EXPERIENCES

In the event medical problems occur in connection with this study, the VAMC will provide medical care for you. Eligibility for medical care is based upon the usual VA eligibility policy and is not guaranteed by participation in this research study. In case of adverse (bad) effects, or physical injury resulting from this study, eligible veterans are entitled to medical care and treatment.

Compensation may or may not be payable in the event of physical injury arising from this study under applicable federal law. Further information about compensation and medical treatment may be obtained from medical administration at this VA Medical Center at (601) 362 4471 x1231.

If you develop a medical problem related to the study or have any question concerning the study, you can contact Dr. Mittal at (601) 362-4471 (#5102) or Dr. Torres at (601) 362-4471 (#4152) during work hours. After hours call the Jackson VAMC operator at (601) 362-4471 and ask the operator to connect you with Dr. Mittal or Dr. Torres. If neither of them can be reached, ask to speak with the staff psychiatrist on-call. You may also leave a message for the research team at (800) 250-9148.

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COMPENSATION

You will receive $40 for each interview you complete, to compensate you for your time.

RESEARCH SUBJECT'S RIGHTS

You may discuss your rights as a research subject with the Chairman of the G.V. (Sonny) Montgomery VAMC Institutional Review Board, James G. Wilson, M.D., 1500 E. Woodrow Wilson Blvd., Jackson, Mississippi, 39216, at telephone number (601) 364-1315 or you may contact the VAMC patient advocate at 601-362-4471 x1253.

All information obtained in this study will remain confidential. Study records may only be seen by study investigators, at both Jackson, MS and Little Rock, AR VA Medical Centers, and the Institutional Review Board, Jackson, MS. Any information obtained during this study and identified with you as a subject will remain confidential and will be disclosed only with your permission. Your information, in all cases, will be treated as confidential except as otherwise prohibited by federal or state law. The results of this research may be used or reported in a scientific presentation or publication, but you will not be personally identified and your confidentiality will be maintained.

We will let you and your physician know of any important discoveries made during this study which may affect you, your condition, or your willingness to participate in this study.

I have read the above statement and have been able to ask questions and express concerns, which have been satisfactorily responded to by the investigator. I understand the purpose of the study as well as the potential benefits and risks that are involved. I hereby give my informed and free consent to be a participant in the study. I have been given a copy of this consent form.

Participant _____ Date _____

Investigator _____ Date _____

_____

Name of Person Obtaining Informed Consent (please print name)

_____ Date _____

Signature of Person Obtaining Informed Consent

_____ Date _____

Signature of Person Witnessing Informed Consent Signatures

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